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Dated: April 6, 2004

Signature: Tram Anh T. Nguyen
(Tram Anh T. Nguyen)

Docket No.: 022727-0056
(ALLOWED PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Dominick Layfield et al.

Application No.: 09/674,137

Filed: April 26, 1999

Art Unit: 1743

For: RADIATION HANDLING SYSTEM AND
SET

Examiner: J. R. Snay

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

MS Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants thank the Examiner for issuing the March 8, 2004 Notice of Allowance wherein all pending claims in the present application were allowed. Applicants also wish to provide the following comments regarding the "Statement of Reasons for Allowance" (hereinafter the "Statement") which accompanied the Notice of Allowance, in accordance with 37 C.F.R. §1.104(e) and MPEP §1302.14.

In the Statement, the Examiner suggests that the receiving system and fluid handling system of the invention are used for the automated delivery of short-lived radionuclides in a closed system. Applicants wish to clarify that the system of the present invention can be used to deliver a number of biologically active, hazardous or radioactive fluids as claimed, and should not be so narrowly interpreted to include the delivery of short-lived radionuclides only, as suggested by the Examiner.

Further, the Examiner's Statement applies to some, but not all of the claims. That is, some of the allowed claims do not recite the limitations relied upon by the Examiner for

allowance. Applicants thus provide the following reasons for why the remaining claims are allowable over the prior art.

Claims 8-10 are allowable because the prior art fails to disclose or suggest a system for sterile preparation of a fluid radionuclide for use, such system comprising a sterile flow set including an inlet, an outlet, a plurality of stopcocks arranged in a sequence along a flow line to define a plurality of fluid transport segments, and first and second syringes connected to the flow line being operable to form a sterile liquid solution of said radionuclide while it remains in the flow set by repeated ejection from said first syringe to said second syringe and return to said first syringe.

Claim 11 is allowable because the prior art fails to disclose or suggest a fluid handling set for use in receiving a hazardous fluid material and forming a delivery liquid, such set comprising a plurality of at least five stopcocks and tubing interconnecting said plurality of stopcocks to form a closed transport path for handling the hazardous fluid material, each stopcock further having a port for admitting material to or expelling material from said closed transport path.

Finally, claims 12-14 are allowable because the prior art fails to disclose or suggest a device for receiving a hazardous fluid material and forming a delivery liquid such as a reagent, medicine or imaging agent containing said fluid material, such device comprising:

- a plurality of stopcock receptacles arranged along a path,
- a corresponding plurality of servomotors positioned and configured for individually controlling a stopcock each being positioned in one of the receptacles,
- a syringe driver, and
- a controller operative to control said servomotors to form a set of flow segments along a closed transport path for handling the hazardous fluid material, and to control said syringe driver to drive a syringe so that the syringe draws said fluid material into the transport path and moves the fluid material along ones of said flow segments so as to prepare and deliver the delivery fluid.

Therefore, the scope of the allowed claims should not be limited to exclude the delivery of biologically active, hazardous, or radioactive fluids other than short-lived radionuclides, nor is

such a limitation necessary in order to maintain the Notice of Allowance in view of the cited references. Moreover, none of the cited references disclose or suggest a system for sterile preparation of a fluid radionuclide for use, or a fluid handling set for use in receiving a hazardous fluid material and forming a delivery liquid, or a device for receiving a hazardous fluid material and forming a delivery liquid such as a reagent, medicine or imaging agent containing said fluid material, according to the allowed claims.

CONCLUSION

Applicants have provided the following remarks in order to address the statements provided with the Notice of Allowance. None of the cited references discloses or suggests the subject matter of the allowed claims, and the Notice of Allowance should be maintained.

Applicants have submitted this communication in order to clarify the record with respect to the Notice of Allowance. Nevertheless, if any issues require clarification, the Examiner is respectfully requested to contact the undersigned representative in order to resolve such issues promptly.

Dated: April 6, 2004

Respectfully submitted,

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